

## REMARKS

The Office Action dated June 25, 2003, has been received and reviewed. Claims 1-51 are pending in the present application. Claims 1-51 stand rejected. Additionally, the claims are subject to a restriction requirement. Applicants respectfully request reconsideration of the application in view of the arguments below.

### I. Claims

Applicants have withdrawn Claims 17-51 and confirm election of Claims 1-16 for prosecution. Applicants also confirm the election for the species requirement for oxandrolone for the androgenic compound and megestrol acetate for progestin. Applicants wish to change their species election for the vasodilation compound to sildenafil citrate rather than phentolamine hydrochloride. Support for this request may be found in paragraph 18. After careful consideration, Applicants additionally wish for the estrogenic compound to claim conjugated estrogens rather than  $17\beta$ -estradiol. Applicants note that the specification at paragraph 16 states that mixtures and conjugates of the estrogenic compounds may be formed and wish if, necessary, to claim a mixture of the conjugated estrogens rather than one specific estrogen. Applicants will amend the claims at a later date to reflect such election if required by the Examiner.

Additionally, Applicants have amended Claim 4 due to a typographical error. Applicants have also corrected typographical errors within the specification.

### II. Rejections under 35 U.S.C. § 112, second paragraph

Claim 16 stands rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter. Specifically, it is alleged that the phrase "performance on demand" is vague and confusing. Applicants note that the phrase "performance on demand" is known to one of skill in the art that the pharmaceutical composition may be taken as needed to treat for female sexual dysfunction. Furthermore, on page 9, paragraph 33, the specification states that "a performance-on-demand (POD) basis include[es] before or during sexual activity". Accordingly, Applicants submit that one of skill in the art would be able to readily determine the meaning of the phrase "performance on

demand" and respectfully request that the 35 U.S.C. § 112, second paragraph rejection be withdrawn.

### III. Rejections under 35 U.S.C. § 103(a)

Claims 1-51 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Place, U.S. Patent No. 6,284,263, (hereinafter "Place"), in view of Estok, U.S. Patent No. 6,011,043, (hereinafter "Estok"). Applicants traverse this rejection for the reasons set forth below.

To establish a *prima facie* case of obviousness, the prior art reference or references when combined must teach or suggest *all* the recitations of the claim, and there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. M.P.E.P. § 2143. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. M.P.E.P. § 2143.01, citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). To support combining references, evidence of a suggestion, teaching, or motivation to combine must be clear and particular, and this requirement for clear and particular evidence is not met by broad and conclusory statements about the teachings of references. *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). The Court of Appeals for the Federal Circuit has also stated that, to support combining or modifying references, there must be particular evidence from the prior art as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000). Furthermore, as recently affirmed by the Court of Appeals for the Federal Circuit in *In re Sang-su Lee*, a factual question of motivation is material to patentability, **and cannot be resolved on subjective belief and unknown authority.** See *In re Sang-su Lee*, 277 F.3d 1338 (Fed. Cir. 2002). Respectfully, as will be discussed below, the Official Action fails to meet the requirements for a *prima facie* showing of obviousness under § 103.

Applicants submit that Place fails to teach or suggest the elements of Claims 1-16 of the present application. Claims 1 and 16 of the present application recite a

composition for the treatment of a sexual dysfunction comprising a therapeutically effective amount of an estrogenic compound; a therapeutically effective amount of an androgenic compound; a therapeutically effective amount of a vasodilation compound; and a pharmaceutically acceptable carrier. Claim 9 recites a composition for the treatment of a sexual dysfunction comprising a therapeutically effective amount of an androgenic compound, a therapeutically effective amount of a vasodilation compound, and a pharmaceutically acceptable carrier.

Place includes a combination of an estrogen, an androgenic compound and a progestin for use in a buccal drug delivery. Place fails to teach or suggest a composition further comprising a vasodilation compound as recited in Claim 1 of the present application. Applicants note that a progestin often leads to a scheduled withdrawal bleed or period in a high percentage of women undergoing hormone replacement therapy. Therefore, absent a proper therapeutically effective amount as noted in the present application, Place merely notes a composition that leads to a scheduled withdrawal bleed or period in a high percentage of women.

Applicants further submit that Estok fails to teach or suggest all of the elements of Claims 1-16 of the present application. Estok notes that phentolamine may be used in a method of treating sexual dysfunction. Furthermore Estok combines phentolamine with an opiate, namely morphine, with zinc chloride to produce apomorphine. Estok provides no basis for any estrogens or androgens to be used in a pharmaceutical composition as recited in Independent Claims 1, 9 and 16 of the present invention. Furthermore, Estok states that female sexual dysfunction may include orgasmic dysfunction due to clitoral irregularities or disturbances, as well as arousal disorder, which is the inability to engorge and/or lubricate the vaginal wall. *See*, Cols. 1-2, lines 66-67 and 1-3. The present application states that sexual dysfunction is "related to such aspects of female sexuality including overall physiological health of the vagina, integrity of the vaginal epithelium, and the ability of the vagina to produce sufficient lubrication." Applicants further submit the overall health benefits are not disclosed or understood by Estok.

The Office Action states that it would be obvious to combine the cited references in order to make the claimed invention because "it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a

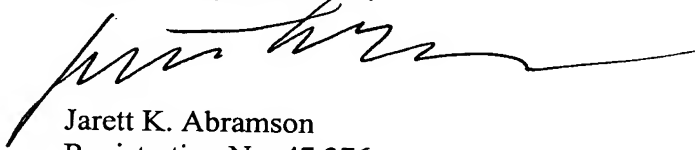
third composition that is to be used for the very same purpose." Applicants submit that these references fail to contain any motivation to combine their teachings as required by *In re Sang-su Lee*. Applicants further submit the overall health benefits are not suggested or taught by Place and Estok. Applicants further submit that one of skill in the art would have not combined the two references due to these benefits. Accordingly, Applicants submit that there is no motivation to combine the teachings of Place and Estok to recite the elements of Independent Claims 1, 9 and 16 of the present invention of which Claims 2-8 and 10-15 depend from respectively. Therefore, Applicants respectfully request reconsideration and withdrawal of the rejections to Claims 1-16.

### CONCLUSION

In view of the remarks presented herein, Applicants respectfully submit that the claims define patentable subject matter. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (919) 854-1400.

It is not believed that an extension of time and/or additional fee(s)-including fees for net addition of claims-are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to our Deposit Account No. 50-0220.

Respectfully Submitted,

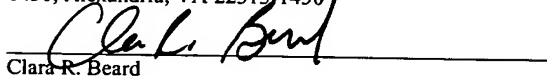


Jarett K. Abramson  
Registration No. 47,376

**USPTO Customer No.: 20792**  
Myers Bigel Sibley & Sajovec, P.A.  
Post Office Box 37428  
Raleigh, NC 27627  
Telephone (919) 854-1400  
Facsimile (919) 854-1401

#### CERTIFICATE OF EXPRESS MAILING

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I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

  
Clara R. Beard